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ATTORNEYS FOR PLAINTIFFS

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CHRISTINA LABAJO, HOWARD CLARK, and BERRY SAIZON

Plaintiffs,

v.

GENERAL NUTRITION CORPORATION and DOES 1-100

Defendants.

CASE NO.: 4:19-cv-01984-HSG

FIRST AMENDED COMPLAINT FOR:

(1) Violation of the Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.*

Plaintiffs Christina Labajo, Howard Clark and Berry Saizon (collectively Plaintiffs), by and through their attorneys, bring this action against Defendant General Nutrition Corporation ("GNC"), and allege as follows based upon their personal experiences as to their own acts and status, and based upon the investigation of their counsel, and information and belief as to all other matters:

NATURE OF THE CASE

1. This is an action primarily seeking declaratory and injunctive relief to restrain GNC from selling dietary supplements mislabeled with unlawful disease claims in California, commonly referred to as "Health Fraud" by federal food and drug regulators (hereinafter the "Products[1]").

2. As explained herein, the U.S. Food and Drug Administration ("FDA"), after a deliberative process and in its final rule in implementing regulations defining the use of structure/function claims on dietary supplements, determined that supplements cannot expressly or impliedly claim to lower cholesterol because it implies treatment for coronary heart disease, rendering the claim misleading and making the product classified as a drug subject to pre-approval based on safety and efficacy. Despite the misleading nature of cholesterol claims on supplements, GNC labels five supplements as being able to maintain and/or support normal or healthy cholesterol levels, without clarifying that they cannot lower cholesterol by stating that they may only maintain cholesterol levels that are already within a normal range, which FDA has said is necessary to avoid implying treatment for hypercholesterolemia and coronary heart disease.

3. Similarly, after the same deliberative process and within the same final rule, FDA determined that dietary supplements cannot expressly or impliedly claim to build, strengthen or maintain bones in menopausal women because it misleadingly implies treatment for osteoporosis, a condition typically experienced by women who have gone through menopause and makes the product a drug subject to pre-approval based on safety and efficacy. Yet, GNC labels three supplements targeted towards menopausal women as able to help build, support, and/or maintain bones.

[1] The term Products used herein refers to GNC Healthy Cholesterol Formula (Exhibit 1), GNC Policosanol (Exhibit 2), GNC Ultra 35 Probiotic Complex with Cholesterol Support (Exhibit 3), GNC Probiotic Solutions Adult 50 Plus (Exhibit 4), GNC Women's Ultra Mega 50 Plus Vitapak (Exhibit 5), GNC Women's Ultra Mega Menopause Vitapak (Exhibit 6), and GNC Women's Ultra Mega 50 Plus (Exhibit 7).

4. The labeling of GNC's Products as being able to cure, treat, mitigate or prevent hypercholesterolemia, coronary heart disease, and/or osteoporosis in menopausal women is both unlawful, it is also a "Health Fraud" because GNC's Products have not been approved as safe and effective for these intended purposes. Under the U.S. Food, Drug and Cosmetic Act ("FDCA") and identical provisions in California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875, *et seq* ("Sherman Law"), products that claim to cure, treat, mitigate or prevent diseases or conditions like hypercholesterolemia, coronary heart disease and osteoporosis are defined as drugs. Sherman Law § 109925 and FDCA § 201(g)(1). Drugs may not be manufactured, labeled or sold without prior approval of FDA. 21 U.S.C. §§ 331(d) and 355(a); Sherman Law § 111550. In violation of these laws, GNC's Products shown in Exhibits 1-7 are labeled to cure, treat, mitigate or prevent hypercholesterolemia (i.e., high cholesterol), coronary heart disease, and/or osteoporosis without prior FDA approval. This identical conduct serves as the sole factual basis of each state law cause of action brought by this Complaint, and Plaintiffs do not seek to enforce any of the state law claims raised herein to impose any standard of conduct that exceeds that which would violate the FDCA and regulations adopted pursuant thereto. Thus, Plaintiffs' state law claims are not preempted by the FDCA because Plaintiffs' claims for state law violations seek to enforce the same standard of conduct required by federal law and Plaintiffs' state law claims are based upon GNC's breach of that standard of conduct. For any of Plaintiffs' state law causes of action, the allegations supporting those causes of action and any forms of relief sought for those state law causes of action, Plaintiffs expressly disclaim any attempt to hold GNC to a higher standard of conduct than what is required under federal law, and do not seek any form of relief based on conduct exceeding that which is required under federal law. All state law causes of action asserted in this Complaint, the allegations supporting those state law causes of action asserted herein and any forms of relief sought for those state law causes of action asserted herein shall be read consistent with the limitations set forth in this paragraph.

5. Accordingly, Plaintiffs bring this action pursuant to Bus. & Prof. Code § 17203 to enjoin GNC from continuing to sell dietary supplements California labeled with the unlawful disease or treatment claims alleged throughout this Complaint.

JURISDICTION AND VENUE

6. Plaintiffs filed their case in the Superior Court of California, for the County of San Francisco, asserting jurisdiction and venue pursuant to Cal. Civ. Code §§ 395.5, 410.10 and 1780(d) over the claims raised in this Complaint for the following reasons: (i) GNC regularly sells, advertises, markets and/or distributes the Products in San Francisco County and throughout the State of California; (ii) a substantial portion of the underlying transactions and events complained of herein occurred in, and Plaintiff Clark resides in, San Francisco County; and (iii) Plaintiff Clark is a citizen and resident of California who resides in San Francisco County and purchased GNC's Products in San Francisco County. Attached hereto as Exhibit 8 is a declaration in compliance with Cal. Civ. Code § 1780(d). GNC removed Plaintiffs' case on April 12, 2019 based on diversity jurisdiction under 21 U.S.C. § 1332(a)(1), asserting complete diversity exists between Plaintiffs and GNC, and the amount in controversy satisfies 28 U.S.C. § 1332(a). *See* Doc. No. 1.

THE PARTIES

7. Plaintiff Christina Labajo is a citizen of the State of California and a resident of San Bernardino County, California. In or around March 2017, Ms. Labajo purchased at least one of GNC's Women's Ultra Mega Menopause Vitapak product from GNC stores in San Bernardino County, California, and paid around $45.00 for the product. The GNC Women's Ultra Mega Menopause Vitapak Ms. Labajo purchased specifically indicated it was a "Menopause Formula" with ingredients that "act as mild estrogens." The GNC Women's Ultra Mega Menopause Vitapak product Ms. Labajo purchased was also labeled as being a clinically studied multivitamin, as being able to "help[] build and maintain bone density," and as containing a formula of vitamins and minerals "shown to support natural bone building." The GNC Women's Ultra Mega Menopause Vitapak product Ms. Labajo purchased was also labeled as supporting "heart and cholesterol health," as providing support "for cardiovascular system function," and "healthy blood lipid levels." Ms. Labajo purchased GNC's products relying, in part, on these labeling statements made on the product's label believing the product was lawfully marketed to cure, treat, prevent or mitigate osteoporosis and coronary heart disease, and more effective than other similar dietary supplements sold by other manufacturers that were not labeled to help treat, prevent or mitigate osteoporosis or coronary heart disease. Had the

GNC product that Ms. Labajo purchased not stated or implied that they could help cure, treat, prevent or mitigate osteoporosis and coronary heart disease, this would have affected Ms. Labajo's purchasing decisions in that she either would not have purchased the GNC product, she would not have been willing to pay the price she did for the GNC product, she would have purchased a lesser quantity of the GNC product, she would have purchased another dietary supplement product, or she would have purchased a similar dietary supplement that was less expensive.

8. Plaintiff Howard Clark is a citizen of the State of California and a resident of San Francisco County, California. Between July 2016 and February 2017, Mr. Clark purchased at least the following GNC dietary supplements: GNC Healthy Cholesterol Formula, GNC Probiotic Solutions Adults 50 Plus and GNC Ultra 35 Probiotic Complex with Cholesterol Support. Mr. Clark purchased these products from GNC stores in San Francisco County, California and paid between $9.00 and $40.00 for each of the products purchased. The Healthy Cholesterol Formula product Mr. Clark purchased was prominently labeled as able to "support[] normal, healthy cholesterol & triglyceride levels with clinically studied black tea extract." The Probiotic Solutions Adults 50 Plus product that Mr. Clark purchased was prominently labeled as "support[ing] healthy cholesterol & vitamin D levels." The Ultra 35 Probiotic Complex that Mr. Clark purchased was prominently labeled as "[c]linically studied support for healthy cholesterol levels," which is reinforced on the back label which states the product contains "[s]pecialized probiotic strains for cholesterol support." Mr. Clark purchased GNC's products relying, in part, on the above-identified labeling statements made on the products' labels believing they were lawfully marketed to help lower his cholesterol level, and thereby help cure, treat, prevent or mitigate coronary heart disease, and more effective than other similar dietary supplements sold by other manufacturers that were not labeled to help lower cholesterol level. Had the GNC products that Mr. Clark purchased not stated or implied that they could help lower his cholesterol level, this would have affected Mr. Clark's purchasing decisions in that he either would not have purchased the GNC products, he would not have been willing to pay the price he did for the GNC products, he would have purchased a lesser quantity of the GNC product, he would have purchased other dietary supplement products, or he would have purchased a similar dietary supplement that was less expensive.

9. Plaintiff Berry Saizon is a citizen of the State of California and a resident of Los Angeles County, California. Between October 2017 and February 2018, Mr. Saizon purchased at least the following GNC dietary supplements: GNC Healthy Cholesterol Formula and GNC Probiotic Solutions Adults 50 Plus. Mr. Saizon purchased these products from GNC stores in Los Angeles County, California and paid around $20.00 for the GNC Healthy Cholesterol Formula and around $40.00 for the GNC Probiotic Solutions Adults 50 Plus. The GNC Healthy Cholesterol Formula Mr. Saizon purchased was prominently labeled as able to "support[] normal, healthy cholesterol & triglyceride levels with clinically studied black tea extract." The GNC Probiotic Solutions Adults 50 Plus that Mr. Saizon product was prominently labeled as "support[ing] healthy cholesterol & vitamin D levels." Mr. Saizon purchased GNC's products relying, in part, on the above-identified labeling statements made on the products' labels believing they were lawfully marketed to help lower his cholesterol level, and thereby help cure, treat, prevent or mitigate coronary heart disease, and more effective than other similar dietary supplements sold by other manufacturers that were not labeled to help lower cholesterol level. Had the GNC products that Mr. Saizon purchased not stated or implied that they could help lower his cholesterol level, this would have affected Mr. Saizon's purchasing decisions in that he either would not have purchased the GNC products, he would not have been willing to pay the price he did for the GNC products, he would have purchased a lesser quantity of the GNC product, he would have purchased other dietary supplement products, or he would have purchased a similar dietary supplement that was less expensive.

10. General Nutrition Corporation is a corporation organized under the law of the Commonwealth of Pennsylvania. General Nutrition Corporation is the successor-by-merger of GNC Franchising, LLC, a Pennsylvania corporation. General Nutrition Corporation's principal place of business is located at 300 Sixth Street, Pittsburgh, Pennsylvania 15222. General Nutrition Corporation is a health and wellness company that sells various nutritional supplements and vitamins throughout the country. General Nutrition Corporation is identified as the "Distributor" of the Products at issue in this lawsuit. *See* Exhibits 1-7.

11. Defendants Does 1 to 100, inclusive, are sued under fictitious names pursuant to Code of Civil Procedure section 474. Plaintiffs allege, based on information and belief, that each of the

defendants sued under fictitious names is in some manner responsible for the wrongs and damages alleged below, in so acting was functioning as the agent, servant, partner, and employee of General Nutrition Corporation, and in taking the actions mentioned below was acting within the course and scope of his or her authority as such agent, servant, partner, and employee, with the permission and consent of General Nutrition Corporation or other Doe co-defendants.

FACTUAL ALLEGATIONS

BACKGROUND OF DRUG AND DIETARY SUPPLEMENT LAWS AND REGULATIONS

12. The purpose of food and drug laws, including the FDCA, FDA regulations and the Sherman Law, is consumer protection. These laws and regulations were enacted, in part, to prohibit the sale of misbranded food and drugs.

13. Amongst other things, the FDCA and Sherman Law require companies wishing to sell a "drug," defined as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal," to prove to the FDA that it is safe and effective prior to marketing it. 21 U.S.C. § 321(g)(1)(B); Sherman Law § 109925(b).

14. To be proven safe and effective as a new drug, drug companies must first test it and send FDA's Center for Drug Evaluation and Research ("CDER") the evidence from these tests to prove the drug is safe and effective for its intended use. A team of CDER physicians, statisticians, chemists, pharmacologist, and other scientists review the company's data and proposed labeling to determine whether the drug's health benefits outweigh its known risks.[2]

15. It is a violation of federal and California law to sell a new drug without prior approval by FDA. 21 U.S.C. § 355(a); Sherman Law § 111550.

16. A dietary supplement, unlike a drug, is a food intended to supplement the diet that bears or contains a dietary ingredient such as a vitamin, mineral, herb or other botanical, or amino acid. 21 U.S.C. § 321(ff).

[2] *See* FDA "How Drugs are Developed and Approved" available online at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm.

17. Foods, including dietary supplements, are misbranded if they characterize the relationship of a nutrient to a disease or health-related condition unless made in accordance with the FDCA. 21 U.S.C. § 343(r)(1); Sherman Law § 110670.

18. A statement characterizing the relationship of a nutrient to a disease or health-related condition on a dietary supplement may be made only if, "the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A).

19. A description of the role of a nutrient or dietary ingredient intended to affect the structure or function in humans is commonly referred to as "structure/function" claims. A structure/function claim may only be made if "the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading." *Id*. § 343(r)(6)(B).

20. Importantly, a dietary supplement may not explicitly or implicitly claim to diagnose, cure, mitigate, treat, or prevent a specific disease or class of diseases. 21 U.S.C. § 343(r)(6)(C). For purposes of this law, a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (*e.g.,* cardiovascular disease), or a state of health leading to such dysfunctioning (*e.g*., hypertension); except that diseases resulting from essential nutrient deficiencies (*e.g*., scurvy, pellagra) are not included in this definition. 21 C.F.R. 101.93(g).

21. Pursuant to 21 C.F.R. § 101.93(g)(2), a statement on a dietary supplement claims to diagnose, cure, mitigate, treat, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(iv) Has an effect on a disease or diseases through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

(C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(x) Otherwise suggests an effect on a disease or diseases.

22. Claims that a product can cure, mitigate, treat, or prevent a disease require prior approval by the FDA and may be made only for products that are approved drug products, or for foods with FDA-approved "health claims." 21 U.S.C. § 355(a) (drugs); 21 C.F.R. 101.93 (f) (food). Failure to obtain prior FDA approval of such a claim in either case renders the claim illegal in violation of 21 C.F.R. 101.93 (f) if a food, or 21 U.S.C. § 355(a) if a drug.

23. The promotion, advertisement, distribution or sale of substances represented as being effective to diagnose, cure, mitigate, treat, or prevent disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven to and approved by the FDA as safe and effective for such purposes, is called "Health Fraud." FDA Compliance Policy Guide 120.500 Health Fraud.[3]

24. FDA classifies Health Fraud as a "major economic cheat" even when a person's health is not directly at risk. *Id.*

25. Even if a Health Fraud does not pose a direct risk to a person's health, it can be an indirect health risk when a person relies on a Health Fraud in delaying or discontinuing appropriate medical treatment. *Id*.

GNC'S HEALTH FRAUD

26. GNC sells several products which explicitly or impliedly claim to treat, cure, prevent or mitigate hypercholesterolemia, coronary heart disease and/or osteoporosis without being approved by FDA as being safe or effective for these purposes. Although the products are labeled to treat, cure, prevent or mitigate these diseases or conditions, the products have not been scientifically proven to and approved by the FDA as safe or effective at mitigating, treating, curing or preventing any disease or condition. Accordingly, GNC's products described below are Health Frauds.

Products Claimed to Cure, Mitigate, Treat or Prevent Hypercholesterolemia and Coronary Heart Disease

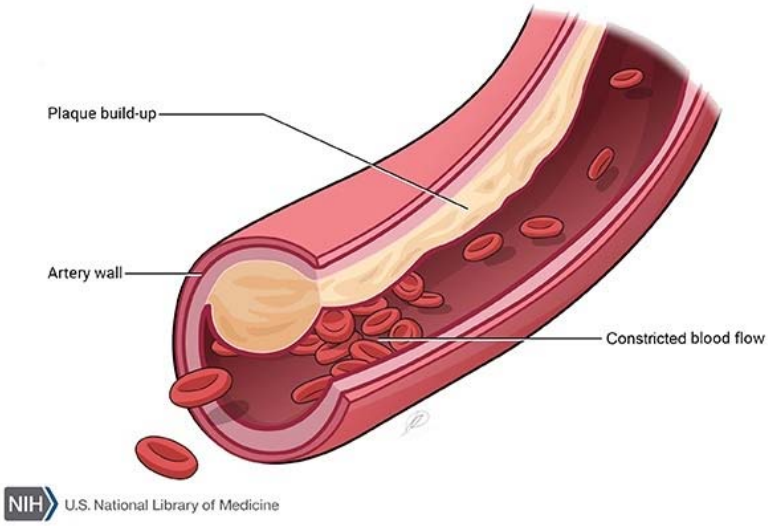
27. Hypercholesterolemia is a condition characterized by high levels of cholesterol in the blood. While the body needs cholesterol to build cell membranes and make certain hormones, too much cholesterol increases a person's risk of developing heart disease and stroke.[4]

28. People with hypercholesterolemia, *i.e.*, high cholesterol levels, have a high risk of developing coronary artery disease. This occurs when excess cholesterol in the bloodstream is deposited in the walls of blood vessels, particularly in the arteries that supply blood to the heart

[3] Available online at https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073838.htm.

[4] *See* https://www.nhlbi.nih.gov/health-topics/high-blood-cholesterol.

(coronary arteries). *See* picture below from the U.S. National Institutes of Health. The abnormal cholesterol buildup forms clumps called plaque that narrow and harden artery walls. As the plaque



gets bigger, it can clog the arteries and restrict the flow of blood to the heart. If too much cholesterol builds up, the blood cannot flow through to the heart which can cause a heart attack.

29. Due to the seriousness consequences of hypercholesterolemia, and the many health and concomitant medication considerations that go into its treatment, hypercholesterolemia is not amenable to self-diagnosis and treatment, meaning adequate directions for use cannot be written so that a layperson can use a product intended to treat hypercholesterolemia safely.[5] FDA has not approved over-the-counter medicines to treat hypercholesterolemia, and instructs consumers to consult their physicians about medicines to help treat the condition.[6] GNC's products described herein have not been approved by FDA as safe and effective for treatment of hypercholesterolemia. Any claim that a dietary supplement can treat, cure, prevent or mitigate hypercholesterolemia or coronary heart disease is a drug claim, and a Health Fraud as it has not been approved by FDA.

30. After the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which established regulatory requirements and procedures for structure/function claims,

[5] *See, e.g.*, FDA Warning Letter to Multimmunity, Inc. dated September 25, 2014 available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm417431.htm.

[6] *See* FDA, High Cholesterol -- Medicines To Help You available online at https://www.fda.gov/ForConsumers/ByAudience/ucm118595.htm.

FDA took public comments and issued regulations to help delineate what would be lawful structure/function claims, and unlawful drug claims. *See* Final Rule on the Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000-01 (Jan. 6, 2000) (to be codified at 21 C.F.R. Part 101) (hereinafter, "Final Rule"). This included claims on dietary supplement regarding cholesterol levels. *Id*. at 1015-19.

31. FDA has long acknowledged that many people think of cholesterol solely in terms of the negative role of high cholesterol and heart disease. Information readily available to consumers on the internet advises of the link between high cholesterol and coronary heart disease.[7]

32. Due to consumer perception linking high cholesterol with heart disease, the availability of information discussing the association between high cholesterol levels and coronary heart disease, the serious health consequences resulting from hypercholesterolemia, and the need for professional advice to treat hypercholesterolemia, FDA undertook careful consideration and deliberation in determining what might be considered an acceptable structure/function claim for cholesterol levels made in the labeling of dietary supplements, and what would be considered an unlawful disease claim prohibited by 21 C.F.R. § 101.93. *See* Final Rule at 1015-18.

33. FDA acknowledged that references in dietary supplement labeling to physiologic markers or symptoms of a disease that are quantifiably linked to that disease in an official government health agency summary statement or consensus report, such as high cholesterol and coronary heart disease, would be appropriately treated as implied disease claims. Final Rule at 1018. FDA specifically noted that hypercholesterolemia is not just a physiologic marker for coronary heart disease, but is a disease condition itself. *Id*.

34. Thus, any claim that a dietary supplement can lower cholesterol, explicit or implicit, is an unlawful drug claim and not a permissible structure/function claim. Final Rule at 1019. FDA

[7] *See, e.g.*, "What causes high cholesterol?" available at https://www.medicalnewstoday.com/articles/9152.php; "High cholesterol" available a t https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/symptoms-causes/syc-20350800; and "High Cholesterol Risk Factors: available at https://www.webmd.com/cholesterol-management/high-cholesterol-risk-factors.

determined this despite the then U.S. Surgeon General advocating for the ability of dietary supplements to be marketed for lowering cholesterol due to the prevalence of heart disease. *Id*. FDA concluded that claiming a dietary supplement can lower cholesterol is prohibited because the use of ineffective therapies in persons with elevated cholesterol, which can delay or prevent effective treatment, itself poses significant public health risks. *Id*.

35. Even though an explicit or implicit claim that a dietary supplement can lower cholesterol is an unlawful disease claim because elevated cholesterol level is a sign of hypercholesterolemia and an important risk factor for heart disease, having cholesterol within the normal range is not a sign or risk factor of disease.

36. Due to the tension between consumer understanding of the link between high cholesterol levels and heart disease, and the recognition that normal cholesterol levels are important, to ensure that a dietary supplement's label does not misleadingly imply the ability to cure, mitigate, treat or prevent high cholesterol, FDA determined that claims linking a substance and cholesterol level must make clear that it can only support or maintain cholesterol levels for people whose cholesterol levels are already in a normal range. Final Rule at 1018-19.

37. FDA also considered whether maintaining "healthy cholesterol" levels would be an acceptable structure/function claim. Final Rule at 1015. Many consumers understand there is a difference between high-density lipoprotein, often called the "good cholesterol" and low-density lipoprotein, often called "bad cholesterol."[8] Given this understanding, FDA determined that references to "healthy cholesterol" could be misleading as this term often refers to high density lipoproteins which are believed to be beneficial. *Id*. at 1019.

38. FDA thus rejected comments suggesting that a dietary supplement labeled as supporting "normal" or "healthy" cholesterol levels does not imply treatment for hypercholesterolemia and coronary heart disease, because it implies lowering "bad cholesterol," or helping with "good cholesterol." Final Rule at 1018-19. The example FDA gave of an acceptable structure function claim for cholesterol that would not misleadingly suggest lowering "bad" cholesterol, or raising "good"

[8] *See* https://www.cdc.gov/cholesterol/ldl_hdl.htm.

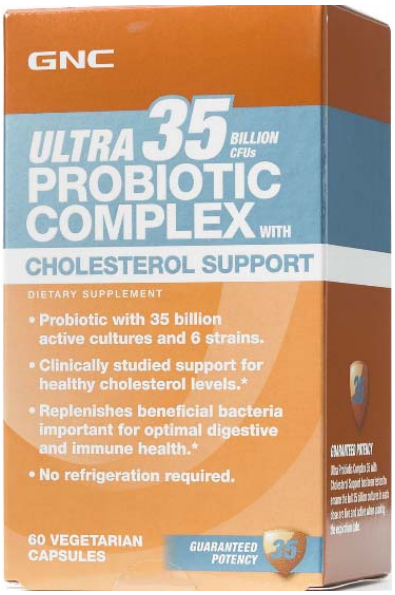
cholesterol is, "helps to maintain cholesterol levels that are already within the normal range." *Id*. at 1019.

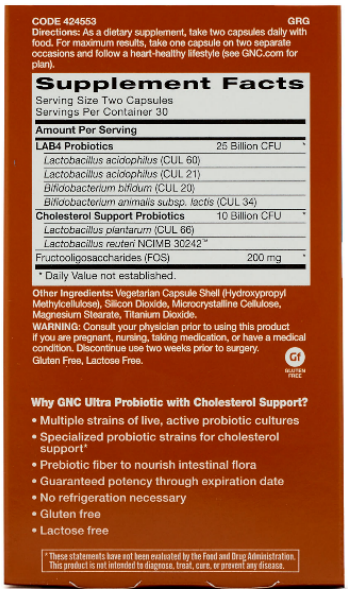
39. Despite FDA's clear guidance that any claim on a dietary supplement about cholesterol level must make it clear that it can only help maintain or support cholesterol levels that are already within the normal range so that it is not implying that it can help cure, treat, prevent or mitigate hypercholesterolemia and/or coronary heart disease, GNC sells several dietary supplements implying that they can help lower "bad" cholesterol levels, or raise "good" cholesterol levels, because they state they can support healthy or normal cholesterol levels as shown and described below.

40. GNC Healthy Cholesterol Formula (Exhibit 1), Policosanol (Exhibit 2), Ultra 35 Probiotic Complex with Cholesterol Support (Exhibit 3), Probiotic Solutions Adults 50 Plus (Exhibit 4), Women's Ultra Mega 50 Plus Vitapak (Exhibit 5), and GNC's Women's Ultra Mega Menopause Vitapak (Exhibit 6) each implicitly claim to cure, mitigate, treat, or prevent hypercholesterolemia.

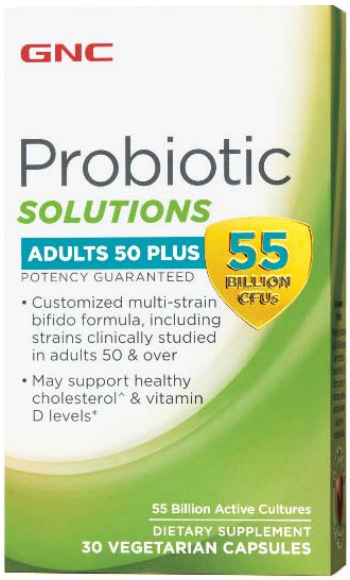
41. As shown above, GNC's "Healthy Cholesterol Formula" is labeled as being a "PHYSICIAN FORMULATED NUTRITION SOLUTION[]" that "[s]upports normal, healthy cholesterol & triglyceride levels with clinically studied black tea extracts." Exhibit 1. The product's name itself, "Healthy Cholesterol Formula," has been found misleading by FDA as referring to high density lipoproteins, or "good cholesterol." *See* Final Rule at 1018-19. Moreover, GNC's Healthy Cholesterol Formula does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.

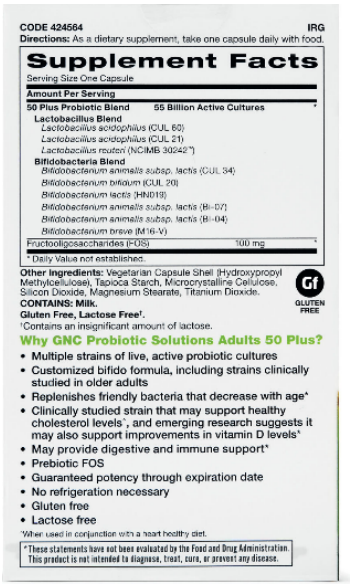
42. As shown above, GNC's Policosanol is labeled, "[m]ay help to maintain normal, healthy cholesterol levels." Exhibit 2. GNC's Policosanol does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.



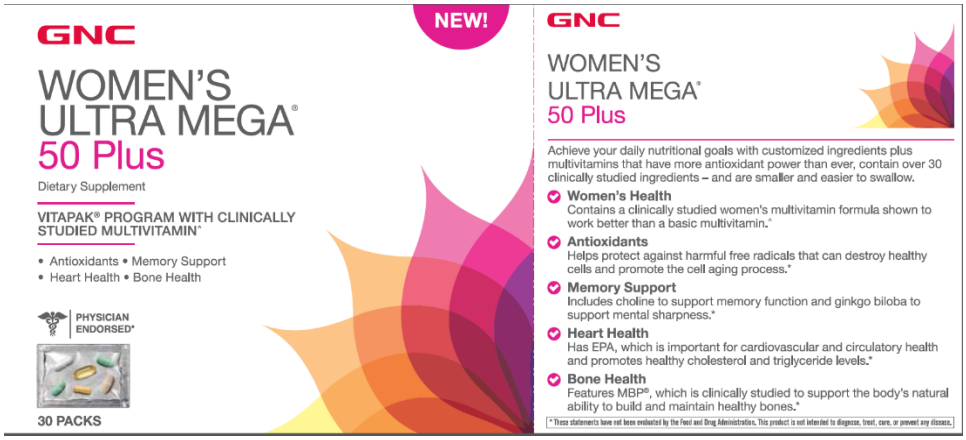


43. As shown above, GNC's Ultra 35 Probiotic Complex with Cholesterol Support is labeled, "[c]linically studied support for healthy cholesterol levels," which is reinforced on the back label which states the product contains "[s]pecialized probiotic strains for cholesterol support." Exhibit 3. GNC's Ultra 35 Probiotic Complex with Cholesterol Support does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.

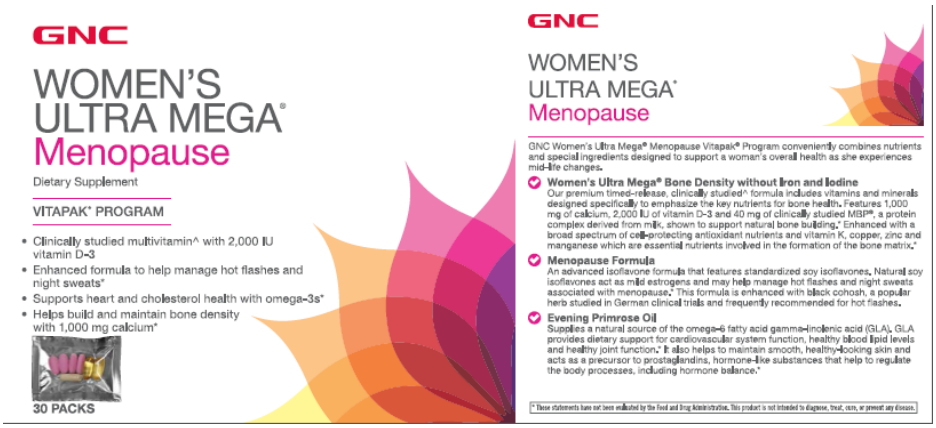




44. As shown above, GNC's Probiotic Solutions Adult 50 Plus is labeled, "[m]ay support healthy cholesterol^ & vitamin D levels." Exhibit 4. The back states it is, "[c]linically studied strain that may support healthy cholesterol levels, and emerging research suggests it may also support improvements in vitamin D levels." Exhibit 4. GNC's Probiotic Solutions Adults 50 Plus does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.



45. As shown above, GNC's Women's Ultra Mega 50 Plus Vitapak product is labeled as "containing over 30 clinically studied ingredients" for, amongst other things, "Heart Health." Exhibit 5. The product is also labeled that it, "[h]as EPA, which is important for cardiovascular and circulatory health and promotes healthy cholesterol and triglyceride levels." Exhibit 5. GNC's Women's Ultra Mega 50 Plus Vitapak does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.



46. As shown above, GNC's Women's Ultra Mega Menopause Vitapak product is labeled as being able to "support a women's overall health," including "heart and cholesterol health with omega-3s." Exhibit 6. GNC's Women's Ultra Mega Menopause Vitapak product does not state that it will only support cholesterol levels for people whose cholesterol levels are already in a normal range.

47. The labeling of GNC's Healthy Cholesterol Formula, Policosanol, Ultra 35 Probiotic Complex with Cholesterol Support, Probiotic Solutions Adult 50 Plus, GNC's Women's Ultra Mega 50 Plus Vitapak and Women's Ultra Mega Menopause Vitapak as being able to maintain and/or support normal or healthy cholesterol levels, without also stating that they will only maintain and/or support cholesterol levels for people whose cholesterol levels are already in a normal range, implies that the products will help cure, mitigate, treat or prevent hypercholesterolemia and/or coronary heart disease by helping lower bad cholesterol.

48. GNC's Healthy Cholesterol Formula, Policosanol, Ultra 35 Probiotic Complex with Cholesterol Support, Probiotic Solutions Adult 50 Plus, GNC's Women's Ultra Mega 50 Plus Vitapak or Women's Ultra Mega Menopause Vitapak products have not been approved by FDA to cure, mitigate, treat or prevent hypercholesterolemia or coronary heart disease.

49. FDA has issued warning letters to companies selling dietary supplements claiming to maintain cholesterol levels without explaining that they will only maintain cholesterol when it is already within a normal range because their labeling indicated they are intended for use in the cure, mitigation, treatment, or prevention of disease. *See*, *e.g*, FDA Warning Letter to Nature's Health

Company, LLC dated June 30, 2017[9]; FDA Warning Letter to Orgen Nutraceuticals, Inc. dated October 28, 2015.[10]

50. FDA issues warning letters such as these "only for violations of regulatory significance."[11] FDA warning letters are intended "to correct violations of the statutes or regulations" and "communicate[] the agency's position on a matter." *Id*. at 4-2 to 4-3.

Products Claimed to Cure, Mitigate, Treat or Prevent Osteoporosis

51. Osteoporosis, or porous bone, is a disease characterized by low bone mass and structural deterioration of bone, leading to fragility and increased risk of fractures.[12]

52. Certain risk factors are linked to the development of osteoporosis and contribute to the likelihood of developing the disease, including abnormal absence of menstrual periods and low estrogen levels caused by menopause.[13] While menopause is a normal part of aging and not a disease, one of the changes in a woman's body experiencing menopause is bones become less dense and more vulnerable to fracture.[14] Due to the decrease in bone density, post-menopausal women are more vulnerable to osteoporosis.[15]

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[9] Available online at https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm566680.htm.

[10] Available online at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm471279.htm.

[11] FDA, Regulatory Procedures Manual at p. 4-2 (Mar. 2017), available at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf.

[12] https://www.bones.nih.gov/health-info/bone/osteoporosis/overview.

[13] *Id*.

[14] *See* NIH "What Is Menopause?" available online at https://www.nia.nih.gov/health/what-menopause.

[15] *Id*.

53. Menopause happens when a woman's ovaries stop making estrogen.[16] The average age a woman enters menopause is 51 years, but it can happen sooner naturally and will happen if a woman has her ovaries removed. [17]

54. Estrogen normally acts in the body to help inhibit bone resorption (breakdown).[18] Having low amounts of estrogen being produced by the body, or no estrogen, will cause bone breakdown.[19]

55. There is no cure for osteoporosis, but there are a large number of prescription medications and therapy options depending on the patient's health, comorbid diseases and other medications.[20] Given the serious consequences of osteoporosis, and the complexity of treatment options, osteoporosis is a disease that is not amenable to self-diagnosis or self-treatment.

56. In implementing the regulations governing structure/function claims on dietary supplements, FDA commented on the labeling of dietary supplements with claims about supporting bones and/or bone fragility. Final Rule at 1013, 17-18. FDA concluded that while a claim that a nutrient can help build or maintain strong bones, without more, is a permitted structure function claim, when associated with osteoporosis or another condition the same claim is an unlawful disease claim because it implies treatment for osteoporosis. *Id*. at 1008.

57. Given the association between menopause and osteoporosis, FDA concluded that a claim that a dietary supplement can maintain, build, strengthen or support bone health and/or bone

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[16] *See* "Hormones and Healthy Bones" from the National Osteoporosis Foundation, available online at https://cdn.nof.org/wp-content/uploads/2016/02/Hormones-and-Healthy-Bones-1.pdf at 6.

[17] *Id*. at 6; *See* WebMD "Your Guide to Menopause" available online at https://www.webmd.com/menopause/guide/menopause-information#1 (menopause starts around age 51 and completed within 4 years).

[18] For review, *see* Siddiqui, Jawed A. and Nicola C. Partridge. Physiological Bone Remodeling: Systemic Regulation and Growth Factor Involvement. Physiology (Bethesda). 2016 May;31(3):233-45 available online at https://www.physiology.org/doi/full/10.1152/physiol.00061.2014.

[19] *Id*.

[20] *See, e.g.,* https://www.fda.gov/forconsumers/byaudience/forwomen/ucm118551.htm; https://americanbonehealth.org/fda-approved-treatments/; and Tu., Kristi N. et al. Osteoporosis: A Review of Treatment Options. Pharmacy and Therapeutics. 2018 Feb; 43(2): 92–104.

density combined with an express or implied claim about menopause – including targeting the advertising towards post-menopausal women – expressly or impliedly claims that the product can help cure, mitigate, treat or prevent osteoporosis. *See* Final Rule at 1013 (indicating a statement that a dietary supplement can prevent bone fragility in post-menopausal women is a disease treatment or prevention claim); *id*. at 1014 (indicating the required disclaimer that a claim on a dietary supplement had not been reviewed or approved by FDA was insufficient to make a claim about preventing bone fractures in post-menopausal women due to bone loss into a lawful claim); *id*. at 1017 (claiming that product prevents bone fragility in post-menopausal women clearly implies that the product prevents osteoporosis); *id*. at 1018 (claiming that a dietary supplement will maintain normal bone density in post-menopausal women is a disease claim because post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass). Thus, the labeling of a dietary supplement as being able to maintain, build, strengthen or support bones in menopausal women is an unlawful disease claim.

58. Despite FDA's clear guidance that a dietary supplement cannot be labeled as being able to maintain, build, strengthen or support bone health in menopausal women, GNC's Women's Ultra Mega 50 Plus, Women's Ultra Mega 50 Plus Vitapak and Women's Ultra Mega Menopause Vitapak products explicitly or implicitly claim to cure, mitigate, treat or prevent osteoporosis for menopausal women.

59. GNC's Women's Ultra Mega 50 Plus Vitapak, pictured on Page 15 *supra*, by its very name is targeted towards women 50 years and older who are typically menopausal. Exhibit 5.

60. GNC's Women's Ultra Mega 50 Plus Vitapak is labeled as being a "CLINICALLY STUDIED MULTIVITAMIN" for, among other things, "Bone Health." Exhibit 5. GNC's Women's Ultra Mega 50 Plus Vitapak is also labeled to "[f]eature[] MBP®, which is clinically studied to support the body's natural ability to build and maintain healthy bones." Exhibit 5. As GNC's Women's Ultra Mega 50 Plus Vitapak is targeted towards menopausal women and is labeled to build, support and maintain bones, it is unlawfully labeled to cure, treat, prevent or mitigate osteoporosis.

61. GNC's Women's Ultra Mega Menopause Vitapak, pictured on page 16 *supra*, is by its very name explicitly marketed towards menopausal women. Exhibit 6. The back of the product states it includes a "Menopause formula" with ingredients that "act as mild estrogens...".

62. GNC's Women's Ultra Mega Menopause Vitapak is also labeled as being able to "[h]elp[] build and maintain bone density with 1,000 mg calcium." The back of GNC's Women's Ultra Mega Menopause Vitapak states it contains a combination of "clinically studied ... vitamins and minerals designed specifically to emphasize the key nutrients for bone health." Exhibit 6. GNC's Women's Ultra Mega Menopause Vitapak is also labeled as being "shown to support natural bone building," and as containing ingredients "which are essential nutrients involved in the formation of the bone matrix." Exhibit 6. As GNC's Women's Ultra Mega Menopause Vitapak is marketed for menopausal women and is labeled to build, support and/or maintain bone density, it is unlawfully labeled to cure, treat, prevent or mitigate osteoporosis.

63. GNC's Women's Ultra Mega 50 Plus, pictured above, is by its very name targeted towards women 50 years and older who are typically menopausal. Exhibit 7.

64. GNC's Women's Ultra Mega 50 Plus is labeled as being a "CLINICALLY STUDIED MULTIVITAMIN" for, among other things, "Bone Health." Exhibit 7. GNC's Women's Ultra Mega 50 Plus is also labeled as being able to "Strengthen[] bones with calcium and vitamin D-3," and as containing "a potent calcium and vitamin D complex to support strong bones." Exhibit 7. As GNC's

Women's Ultra Mega 50 Plus is targeted towards menopausal women and is labeled to strengthen and support bones, it is unlawfully labeled to cure, treat, prevent or mitigate osteoporosis.

65. The labeling of GNC's Women's Ultra Mega 50 Plus Vitapak, Women's Ultra Mega Menopause Vitapak, and Women's Ultra Mega 50 Plus as being able to build, support, and/or maintain bones implies that the products will help cure, mitigate, treat or prevent osteoporosis because the products are targeted towards menopausal women who typically experience osteoporosis.

66. None of GNC's Women's Ultra Mega 50 Plus, Women's Ultra Mega Menopause Vitapak or Women's Ultra Mega 50 Plus Vitapak products have been approved by FDA for the treatment, prevention, cure or mitigation of osteoporosis.

Labeling Products with Drug or Disease Claims without FDA Approval is Misleading

67. The labeling of products that claim to cure, treat, prevent or mitigate diseases or other health related conditions, when they have not been approved as being safe and effective to do so, is misleading. *See* FDA Health Fraud Scams[21].

68. To the extent GNC's supplements cannot cure, treat, prevent or mitigate the diseases or conditions for which they imply treatment, the labeling of the supplements is false and misleading.

69. Even if GNC's supplements are not completely ineffective for the advertised benefits, the labeling of GNC's products as dietary supplements, and not as over-the-counter ("OTC") or prescription drugs, is still misleading as the labeling omits information that is material to consumers.

70. Congress charged FDA with ensuring that all drugs (*i.e.*, prescription and OTC) are not only safe and effective, but that their labeling adequately informs users of the risks and benefits of the product, and that its labeling is truthful and not misleading.

71. FDA makes its determination on all drug approval (*i.e.*, prescription and OTC) based on a comprehensive scientific evaluation of a product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 355(d).

72. FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the

[21] Available online at https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/default.htm.

product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. 71 Fed. Reg. 3922, 3934 (January 24, 2006).

Prescription Drug Labeling

73. For prescription drugs, the centerpiece of risk management generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate. 71 Fed. Reg. at 3934

74. Labeling, as defined by the FDCA, "means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

75. The requirements for prescription drug labeling are set forth in 21 C.F.R. § 201.56. Amongst other things, prescription drug labeling must include:

a. A summary of the essential scientific information needed for the safe and effective use of the drug;

b. the informative must be informative and accurate

c. the information may not be promotional in tone, and nothing false or misleading may be included;

d. no implied claims or suggestions for use if evidence of safety or efficacy is lacking; and

e. based, whenever possible, on human testing.

76. The FDA approves prescription drug labels based on its analysis of a new drug application or biologics license application, and contains information "necessary for safe and effective use." 71 Fed. Reg 3911-01, 3922 (January 24, 2006).

77. The primary purpose of prescription drug labeling is to give healthcare practitioners the information they need to prescribe drugs appropriately. *Id*. at 3961. The information in prescription drug labeling, and the format it is presented, is to give healthcare professionals the ability to access, read and use drug information. *Id*. at 3923.

78. Amongst other things, prescription drug labeling must include: Highlights of prescribing information that includes the dosage; concise summary of any boxed warnings; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; and adverse reactions. 21 C.F.R. § 201.57(a).

79. Prescription drug labeling must also include Full Prescribing information with appropriate headings and subheadings that detail any boxed warnings; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; adverse reactions; drug interactions; use in specific populations, pregnancy risks; effects on reproductive potential; pediatric use; geriatric use; description including chemical and physical information; clinical pharmacology; nonclinical toxicology; clinical studies; references; proper storage and handling; patient counseling information. 21 C.F.R. § 201.57(b)-(c).

80. The information must be presented in a uniform way, with a specific format and with minimal type size requirements to make reading and understanding the information easy. 21 C.F.R. § 201.57(d).

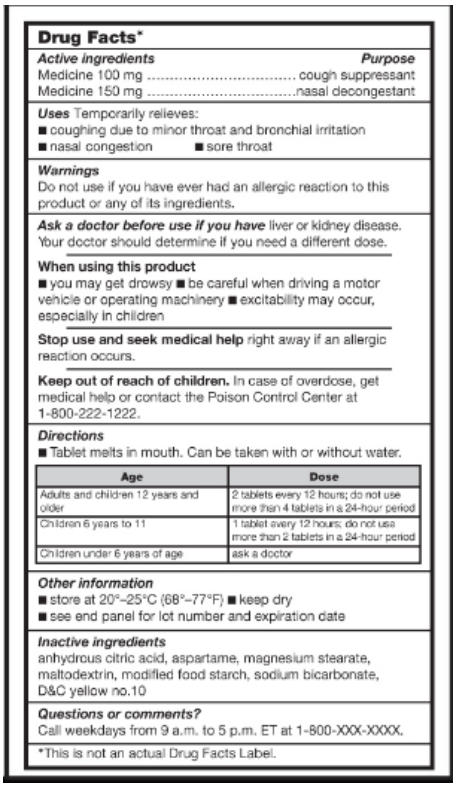
81. The ultimate purpose of prescription drug labeling is to give healthcare practitioners the information they need, in a uniform and easily-readable format, to keep consumers from harm through the use of appropriate drugs. Consumers rely on their health care practitioners to have all of the critical information about a drug when recommending it for a specific purpose. Thus, the failure to label prescription drugs accurately, with all of the required information and in the required format, is material to consumers and it can lead to harm through the misuse of such drugs.

OTC Drug Labeling

82. Even if GNC's Products implied treatment for conditions amenable to self-diagnosis and treatment, allowing them to be classified as OTC drugs, the labeling omits information that is material to consumers. Indeed, proper labeling of OTC drugs may be more material to consumers than prescription drug labeling because there is no professional intermediary, such as a doctor or pharmacist, between the drug and the consumer.

83. As stated by FDA, reading the label of an OTC drug is the most important part of taking care of yourself or your family when using OTC medications, especially because many OTC medicines are taken without seeing a doctor.[22] The label should tell a consumer what a medicine is supposed to do, who should or should not take it, and how to use it.

84. Amongst other things, all OTC drug labels must include "Drug Facts" with a specific graphical design to be a visual cue to consumers for introducing required information as shown below (21 C.F.R. § 201.66(c)(1)):



Drug Facts*

Active ingredients ***Purpose***
Medicine 100 mg ..... cough suppressant
Medicine 150 mg ..... nasal decongestant

Uses Temporarily relieves:
■ coughing due to minor throat and bronchial irritation
■ nasal congestion ■ sore throat

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product
■ you may get drowsy ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children

Stop use and seek medical help right away if an allergic reaction occurs.

Keep out of reach of children. In case of overdose, get medical help or contact the Poison Control Center at 1-800-222-1222.

Directions
■ Tablet melts in mouth. Can be taken with or without water.

Age	Dose
Adults and children 12 years and older	2 tablets every 12 hours; do not use more than 4 tablets in a 24-hour period
Children 6 years to 11	1 tablet every 12 hours; do not use more than 2 tablets in a 24-hour period
Children under 6 years of age	ask a doctor

Other information
■ store at 20°–25°C (68°–77°F) ■ keep dry
■ see end panel for lot number and expiration date

Inactive ingredients
anhydrous citric acid, aspartame, magnesium stearate, maltodextrin, modified food starch, sodium bicarbonate, D&C yellow no.10

Questions or comments?
Call weekdays from 9 a.m. to 5 p.m. ET at 1-800-XXX-XXXX.

*This is not an actual Drug Facts Label.

[22] FDA The Over-the-Counter Medicine Label: Take a Look available online at https://www.fda.gov/drugs/emergencypreparedness/bioterrorismanddrugpreparedness/ucm133411.htm.

85. "Active Ingredients" must have an established name, and list the quantity or proportion of each active ingredient immediately below a prominent title to enable consumers to quickly and systematically compare ingredient within products for similar uses. 64 Fed. Reg. 13254-01, 13260.

86. "Purpose" is the FDA-approved description of the principal intended action of the drug or each active ingredient. 21 C.F.R. § 201.66(c)(3).

87. "Uses" provides the indications for use of the product. 21 C.F.R. § 201.66(c)(4).

88. "Warnings" provides specific information and subheadings including whether the product is for external use only and, as appropriate, for rectal or vaginal use; Reye's syndrome warning if the product contains salicylates; allergic reaction and asthma alert warnings; contraindications when consumers should not use the product unless a doctor directs the usage; preexisting conditions warnings; juvenile warnings; pregnancy warnings; accidental ingestion/overdose warning. 21 C.F.R. § 201.66(c)(5).

89. Directions for use, such as specific age categories, how much to take, how to take, and how often and how long to take. 21 C.F.R. § 201.66(c)(6).

90. Other Information required by the FDA specifically excluding any promotional material as it is generally not necessary for the safe and effective use of the product. 21 C.F.R. § 201.66(c)(7) and 64 Fed. Reg. 13254-01, 13263.

91. Inactive Ingredients are to be listed in accordance with 21 C.F.R. § 201.66(c)(8).

92. Questions or Comments that provides a telephone number for a source to answer questions about the product. 21 C.F.R. § 201.66(c)(9).

93. Having all of the required information, and have it presented in a uniform way, is material to consumers who wish to make an educated decision about what drugs they are putting into their bodies, as well as whether it is the best and/or most economical product for what they are trying to accomplish. The failure to include any of this information on an OTC drug product is not only unlawful, but it prevents consumers from being able to comparative shop for the most appropriate product for their needs.

94. Unless FDA has given a specific exemption from including required information on an OTC drug's label, its inclusion is material to consumers. The omission of any information from the

labeling of a food or drug that is material in light of the claims made for the product or the consequences that may result from using the product deems the product misleading and misbranded. 21 C.F.R. § 1.21(a).

GNC Refused To Cease Its Wrongdoing

95. On November 17, 2017, Mr. Clark and Ms. Labajo, through their counsel and pursuant to California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1782, sent GNC a certified letter notifying GNC of particular violations of Civil Code § 1770, and demanded that GNC correct, repair or otherwise rectify the problems associated with its unlawful behavior which are in violation of Civil Code § 1770 ("CLRA Letter"). A copy of the CLRA Letter is attached hereto as Exhibit 9 (exhibits thereto omitted).[23]

96. GNC failed to respond to the CLRA Letter.

97. To date, the labels of the Products being the unlawful claims detailed herein have not changed, and GNC has yet to respond to the CLRA Letter.

98. As GNC has failed to respond to the CLRA Letter, and the Products' labels have not changed, it appears GNC is and continues to be unwilling to change the labeling of the Products to remove the drug claims identified in the CLRA Letter and throughout this Complaint, or to submit a new drug application with FDA in order to have its products approved as new drugs with appropriate drug labeling.

99. GNC has not stopped using or corrected, repaired or otherwise rectified the unlawful labeling practices identified in the CLRA Letter and described in this Complaint.

FIRST CAUSE OF ACTION
("Unlawful" Business Practices in Violation of
The Unfair Competition Law, Bus. & Prof. Code §§ 17200, *et seq.*)

100. Plaintiffs hereby incorporate all other paragraphs of this Complaint and restate them as if fully set forth herein.

[23] The CLRA Letter also set forth claims regarding abnormal blood glucose levels, inflammation, oxidative stress, and statin therapy in other of GNC's products. However, Plaintiffs are not asserting any claims regarding abnormal blood glucose levels, inflammation, oxidative stress, and statin therapy in GNC's products in this First Amended Complaint.

101. California's Unfair Competition Law ("UCL") defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice. Cal. Bus. & Prof. Code § 17200.

102. A business practice is "unlawful" if it violates any established state or federal law.

103. Sherman Law § 111550 prohibits the sale, delivery or gift of any new drug without approval of a new drug application by FDA or California's Department of Health Services.

104. Sherman Law § 109925 and FDCA § 201(g)(1) define "drug" as, amongst other things, any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals. Any food for which a health claim has been approved by FDA pursuant to FDCA §§ 403(r)(1)(B) and 403(r)(3) for conventional foods, or §§ 403(r)(1)(B) and 403(r)(5)(D) for dietary supplements, is not a drug solely because the label or labeling contains such a claim. Unlike conventional foods, dietary supplements cannot be labeled with health claims based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research.

105. A "new drug" is any drug which has not been proven to be safe and effective for use under conditions prescribed, recommended or suggested in the labeling or advertising thereof. 21 C.F.R. § 321(p); Sherman Law 10998.

106. As explained above, GNC's Products are new drugs as they are labeled as being intended to cure, treat, mitigate or prevent hypercholesterolemia, coronary heart disease and/or osteoporosis in humans. However, none of GNC's Products identified in this complaint have been approved as a new drug by FDA or California's Department of Health Services for these purposes.

107. GNC violated and continues to violate Sherman Law § 111550 through the sale, delivery or gift of each of the new drug products identified herein without approval of a new drug application by FDA or California's Department of Health Services, and hence also violated and continues to violate the "unlawful" prong of the UCL.

108. The Sherman Law also prohibits the advertisement of any food or drug that is misbranded. Sherman Law § 110398. Advertisement for the purpose of the Sherman Law includes any representations about a product including statements on the packaging. Sherman Law § 109885.

109. Sherman Law § 111440 prohibits the manufacture, sale, delivery, holding or offer to sell a misbranded drug, and § 111445 prohibits the misbranding a drug.

110. Food and drugs are misbranded if their labeling is false or misleading in any particular. Sherman Law §§ 110660 and 111330 (respectively).

111. The labeling of a food or drug is misleading if it fails to reveal facts that are material in light of other representations made, or if it fails to include affirmative disclosure of material facts required by FDA regulations promulgated pursuant to the FDCA. 21 C.F.R. § 1.21.

112. The Sherman Law adopts FDA regulations of food and drugs as the law of California. Sherman Law §§ 110100 (food); 110110 (new drugs) 110111 (OTC drugs).

113. GNC's Products labeled as drugs fail to provide material information required by FDA for all drug products as explained above. Due to GNC's omission of this material information, the Products are misbranded and GNC violated, and continues to violate, 21 C.F.R. § 1.21 and Sherman Law §§ 110110 and 110111.

114. Moreover, due to the omission of the material drug information which renders the Products misbranded, GNC violated, and continues to violate, Sherman Law §§ 111440, 111445, 110660, 111330 by misbranding the Products, manufacturing, selling, delivering and offering to sell misbranded Products.

115. GNC's identical conduct that violates the Sherman Law also violates the FDCA, 21 U.S.C. §§ 331(a), (b), (d), (g), 352 and 355, and FDA regulations, 21 C.F.R. § 201.57, 21 C.F.R. § 201.66. This identical conduct serves as the sole factual basis of each cause of action brought by this Complaint, and Plaintiffs do not seek to enforce any of the state law claims raised herein to impose any standard of conduct that exceeds that which would violate the FDCA and applicable FDA regulations.

116. By committing the unlawful acts and practices alleged above, GNC has engaged, and continues to be engaged, in unlawful business practices within the meaning of the UCL.

117. As a result of GNC's unlawful conduct, GNC has obtained money from Plaintiffs, and Plaintiffs have suffered injury in fact and lost money or property. As such, Plaintiffs request that this

Court enjoin GNC from continuing to violate the UCL or violating it in the same fashion in the future as discussed herein pursuant to Cal. Bus. & Prof. Code §17203.

JURY DEMAND

Plaintiffs demand a jury trial on all causes of action and/or issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for relief and judgment against GNC as follows:

A. A declaration and Order enjoining GNC from misbranding, manufacturing, selling, delivering, holding or offering for sale, selling or offering for sale, delivering or proffering for delivery the Products labeled with unapproved drug or disease claims in violation of California's Sherman Law and other applicable laws and regulations as specified in this Complaint;

B. An Order awarding Plaintiffs their costs of suit, attorneys' fees and pre-and post-judgment interest; and

C. Such other and further relief as the Court may deem just and proper.

Dated: December 3, 2019

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